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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/965,571 | 09/27/2001 | Daniel C. Rosenman | HRT-275 | 3677 |

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EXAMINER

FOREMAN, JONATHAN M

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| ART UNIT | PAPER NUMBER |
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3736

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,571

Applicant(s)

ROSENMAN ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 35-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/02, 9/02, 10/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION***Information Disclosure Statement***

The information disclosure statement filed on 8/13/02, 9/23/02 and 10/27/03 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Drawings

1. The drawings are objected to because in Figure 3, the reference numeral "16" does not appear to be associated with the recesses as set forth on page 4, line 7. Additionally, in Figure 4, the reference numeral "26" does not appear to be associated with the outer surface as set forth on page 4, line 20. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 41 and 49 are objected to because of the following informalities: The phrase "the plurality of arms" lacks antecedent basis in line 3 of claim 31. The phrases "the first end", "the first part" and "the second end" lacks antecedent basis in lines 3 and 4 of claim 49 . Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 35 – 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 - 12 of U.S. Patent No. 6,042,554 to Rosenman et al. and claims 1 – 15 of U.S. Patent No. 6,322,526 to Rosenman et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 – 12 and 1 – 15

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of U.S. Patent No. 6,042,554 and U.S. Patent No. 6,322,526 respectively set forth all of the structural limitations in the method steps of the present application. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the valve sizer as claimed in Patents No. 6,042,554 and 6,322,526 with a method including placing the sizer into a patient, adjusting the movable element with the actuator; and removing the sizer from the patient.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 35 - 50 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,814,098 to Hinnenkamp et al.

In reference to claims 35 – 45, Hinnenkamp et al. discloses a method including providing a valve sizer (Col. 4, lines 1 – 8) having: a shaft (318) ; a valve sizing portion (308) having an outer dimension, the valve sizing portion including a movable element (Col. 9, lines 7 – 11) coupled to the distal end of the shaft (Col. 9, lines 29 – 31), the movable element being movable between a first and second position; an indicator (352) located at the proximal end of the shaft, an actuator (334) being operatively coupled to the movable element for moving the element between a first and second position (Col. 9, lines 24 – 29); inserting the distal end of the sizer into a patient so the moveable element is positioned in the valve annulus (Col. 5, line 66 – Col. 6, line 1); adjusting the element by manipulating the actuator at the proximal end of the shaft (Col. 6, lines 1 – 4). The sizer must be

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removed from the patient. A rod (316) coupled to the actuator extends through a portion of the shaft. Rotation of the rod moves the movable element (Col. 9, lines 24 – 29). The outer dimension of the movable element is no more than 19 mm and at least 33 mm (Col. 4, lines 18 – 24).

Hinnenkamp et al. discloses a sizer embodiment where the movable element has a plurality of arms having outer surfaces forming a circular shape (Col. 9, lines 8 – 14; Figure 16) in a plane perpendicular to the longitudinal axis of the shaft. A disk (322) attached to the rod (316) receives pins (328) attached to the arms. Hinnenkamp et al. discloses a sizer embodiment (Figures 12 and 13) where a plurality of camming surfaces are coupled to the shaft, (256) the surfaces being configured to engage and cam a plurality of arms (266) when the actuator is actuated (Col. 8, lines 41 – 50).

In reference to claims 36 – 50, Hinnenkamp et al. discloses a method including providing a valve sizer (Col. 4, lines 1 – 8) having: a shaft (20); a ring mounted to the distal end of the shaft (Col. 4, lines 29 – 31), the ring being movable from a first position to a second position; an actuator (22) mounted to the proximal end of the shaft (Col. 4, lines 27 – 28), the actuator being operatively coupled to the ring for moving the ring (Col. 4, lines 31 – 34); positioning the ring in the valve annulus of a patient (Col. 5, line 66 – Col. 6, line 1); manipulating the actuator so the ring expands and engages the valve annulus (Col. 6, lines 1 – 4). The sizer must be removed from the patient. Hinnenkamp et al. discloses a sizer embodiment where the ring has a first part (38) and a second part (40) slidably coupled to the first part (Col. 4, lines 50 – 52). The second part is received in a recess in the first part, the first part has first and second ends (52). Hinnenkamp et al. discloses a sizer embodiment (Figures 10 and 11) having a first lever (208) coupled to the first end of a first part (Col. 7, lines 46 – 48); a second lever (204) coupled to the second end of the first part (Col. 7, lines 44 – 46), the second lever being rotatable relative to the first lever; and the actuator (218) being

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operatively coupled to at least one of the first and second levers for rotating the first lever with respect to the second lever and for moving the first and second ends (Col. 7, lines 52 – 61).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JMLF


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